

Mauna Kea Technologies

Creators of Cellvizio[®]

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Company Snapshot

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time in vivo microscopic visualization. The Company’s flagship product, Cellvizio®, has received clearance/approval for a wide range of applications in the United States and more than 40 countries around the world. For more information, visit www.maunakeatech.com.

Founded	2000
Office Locations	<ul style="list-style-type: none"> • Paris, France (Headquarters) • Allston, MA, USA • Shanghai, China
Full-Time Employees*	~105

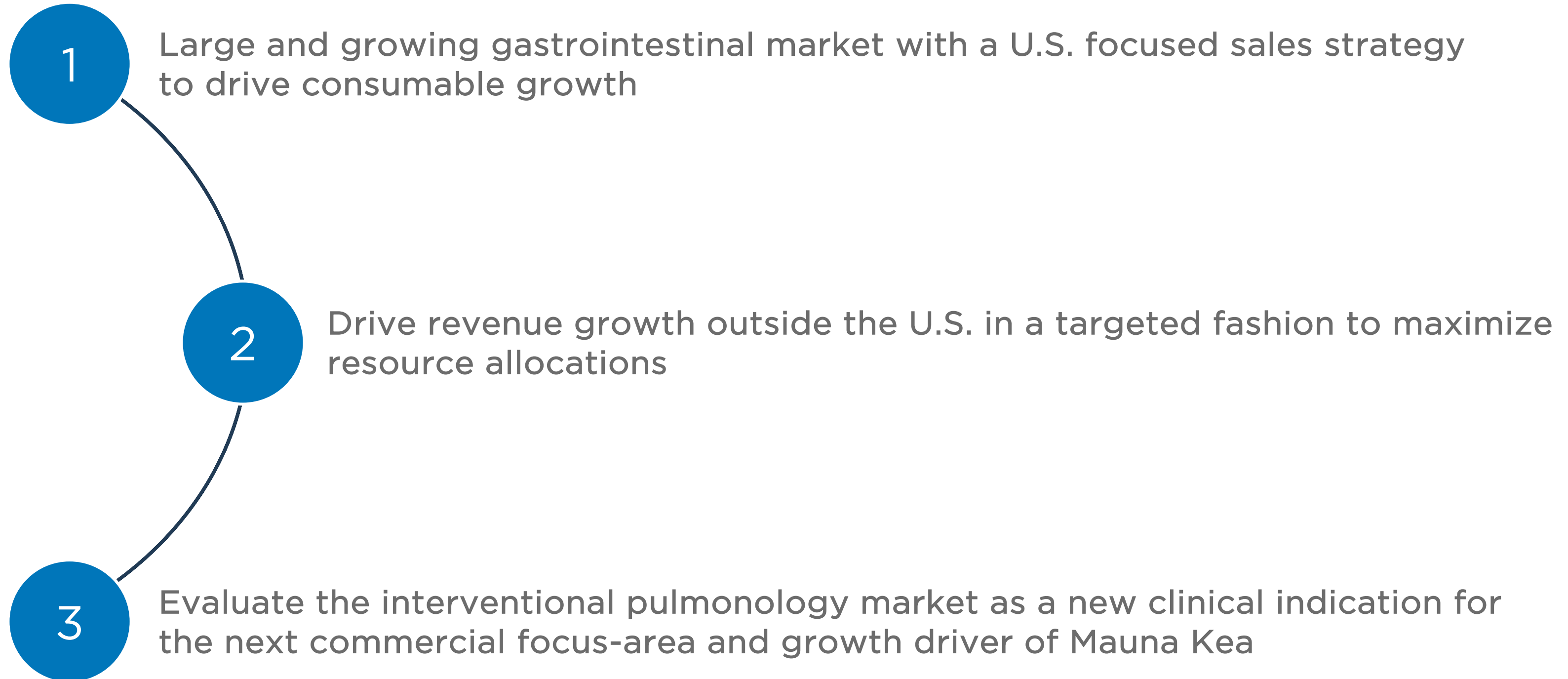
Year of IPO	2011
Exchange/Ticker	Euronext Paris: MKEA
Number of Shares*	25,201,338



Mauna Kea Technologies - A Compelling Platform Opportunity...

- 1 Transformational probe-based and needle-based Confocal Laser Endomicroscopy (CLE) platform
- 2 U.S.-focused growth strategy fueled by proven technology, focused commercial strategy, strong team, broad clinical validation and attractive Medicare reimbursement
- 3 Broad IP portfolio: 247 issued and 24 pending patents on Cellvizio® technologies
- 4 Robust R&D pipeline to drive growth through application and product expansion
- 5 Strong regulatory support: Approved in 40+ countries; 16 U.S. FDA 510(k) clearances
- 6 New seasoned US-based executive leadership to drive commercial acceleration

...Supported by a Focused Value Creation Strategy



What is Cellvizio®? An Adjunct to Existing Biopsy Techniques, Enhancing the Standard of Care...

Most pathologists' labs use conventional microscopy which is antiquated technology that has not evolved in decades



Current Standard

- Random biopsy protocols
- Dead tissue
- Ex vivo
- One image
- Limits ability to make real-time decisions



Cellvizio is the world's smallest microscope; a significant leap forward, advancing pathology technology and shrinking a large system onto the head of a sub-3mm probe



Cellvizio System + Miniprobes

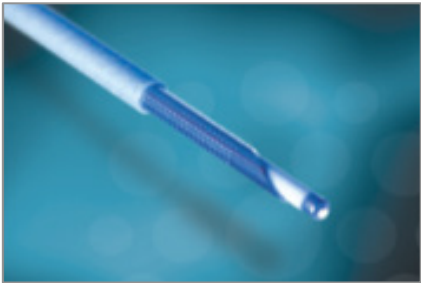
- Targeted biopsies
- Whole, live tissue
- In vivo
- Unlimited number of images
- Facilitates early detection and clinical intervention

...By Integrating With Existing Procedure Workflows and Revealing Key Invisible Information...

The Cellvizio Confocal Laser Endomicroscopy (CLE) platform incorporates seamlessly into the existing procedure workflow via the scope working channel (pCLE), through the needle (nCLE), or with laparoscopic or robotic systems



pCLE
(Probe/Catheter)

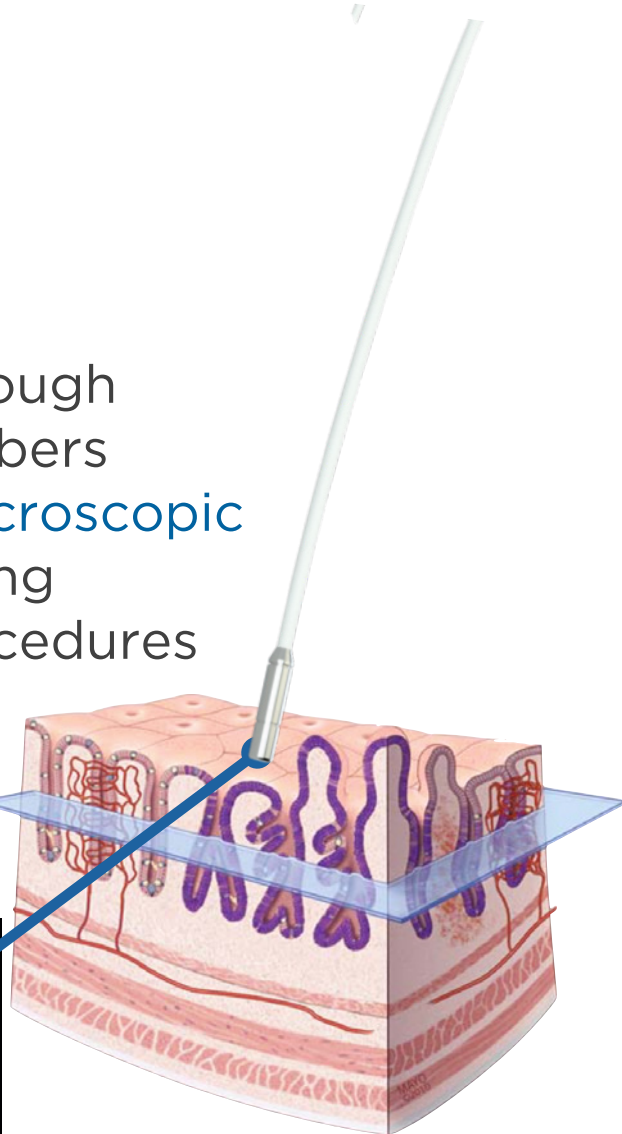
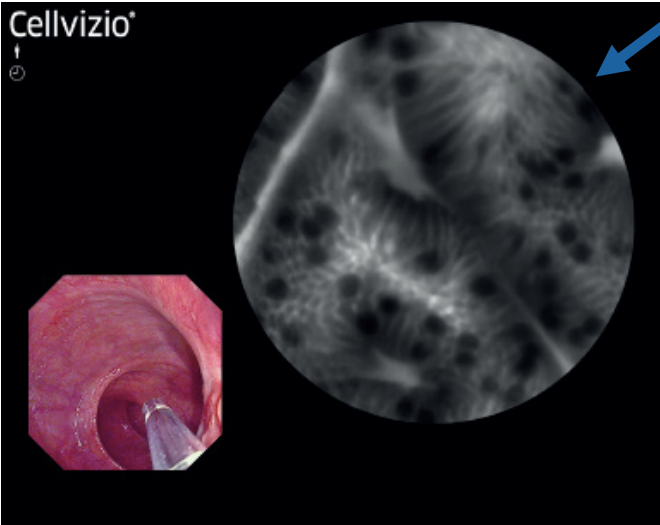


nCLE
(Through the Needle)



pCLE
(Laparoscopic/Robotic)

Proprietary scanning through 30,000 custom optical fibers produces 12 real-time microscopic sections per second during standard endoscopy procedures



...and Enabling Better Informed Patient Management

DETECT DISEASES EARLIER

Confirm disease status and progression early enough to perform clinical intervention

REDUCE MISSED DIAGNOSES

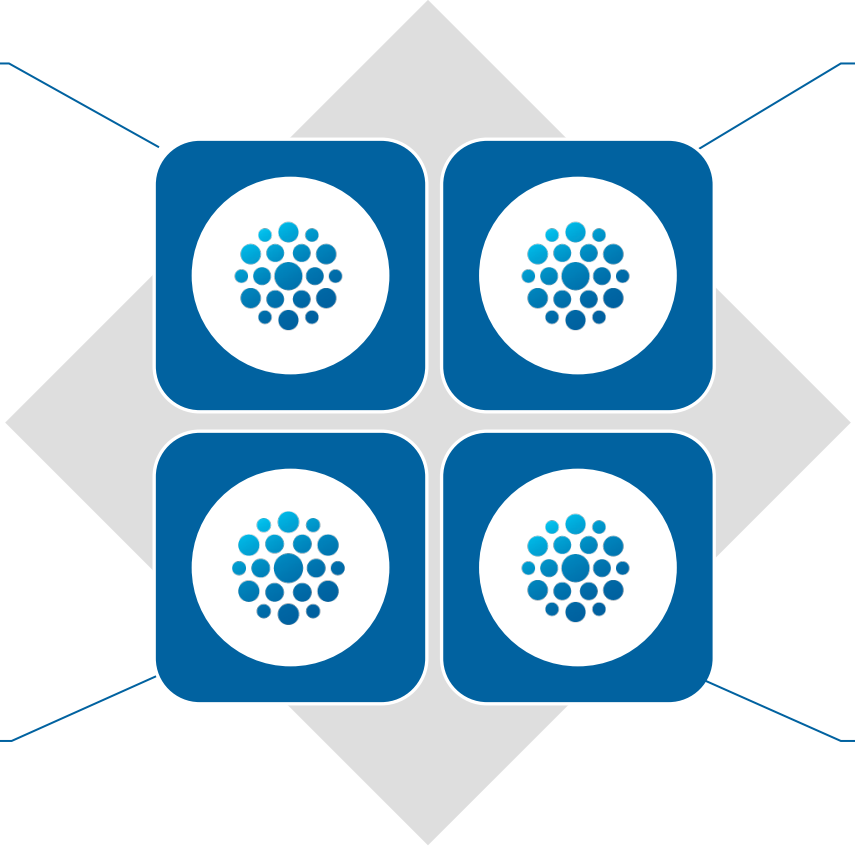
Higher diagnostic yield enables characterizing diseases like Barrett's Esophagus before progression to esophageal cancer

REDUCE UNNECESSARY SURGERIES

Rule-out tumor malignancy with high specificity and sensitivity prior to surgical intervention

PRACTICE CONSERVATIVE MEDICINE

Assess and confirm margins and ensure as much healthy tissue as possible is preserved



Cellvizio adds clinical and economic value at every step of the patient journey, impacting diagnostic outcomes and managing costs, all in real-time

Cellvizio U.S. Gastroenterology Market Opportunity

Hospital Procedures

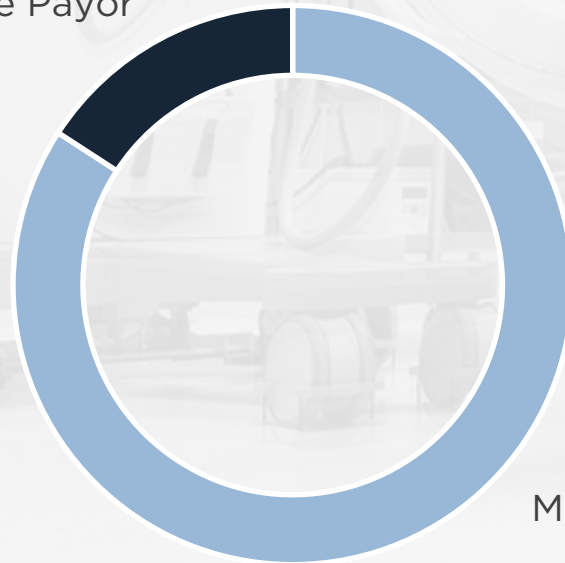
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ASC Procedures

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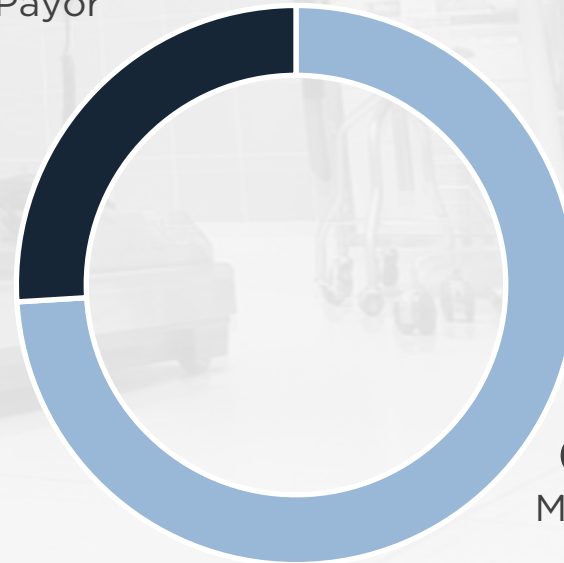
U.S. Market Opportunity

0.4M
Private Payor



2.1M
Medicare

0.3M
Private Payor



0.8M
Medicare

\$2.8B
Annual
Recurring
Revenue

Established U.S. Reimbursement With 3 Dedicated Upper GI Category 1 CPT Codes

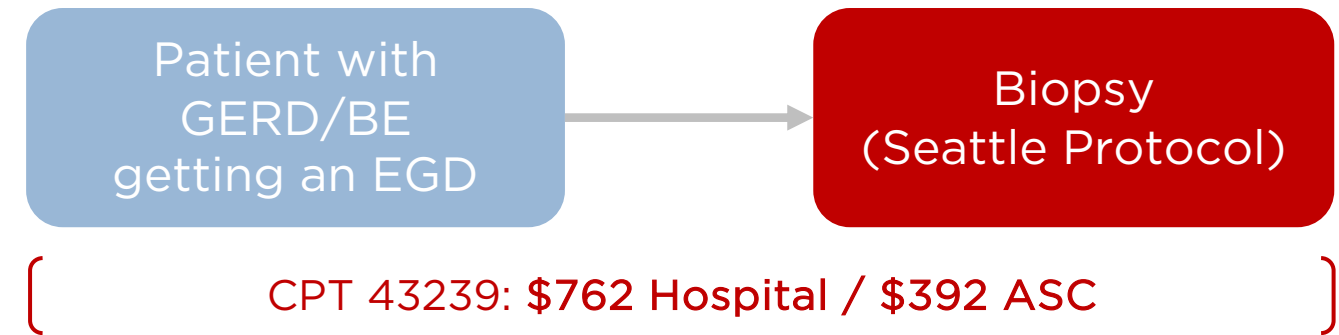
Positive Payment Trends Over the Past 4 Years

- **Dedicated CPT Code 43252:** Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with optical endomicroscopy
- **CMS Covered Services:** Endomicroscopy in upper GI endoscopy procedures, including GERD, Barrett's Esophagus and pancreatic lesions

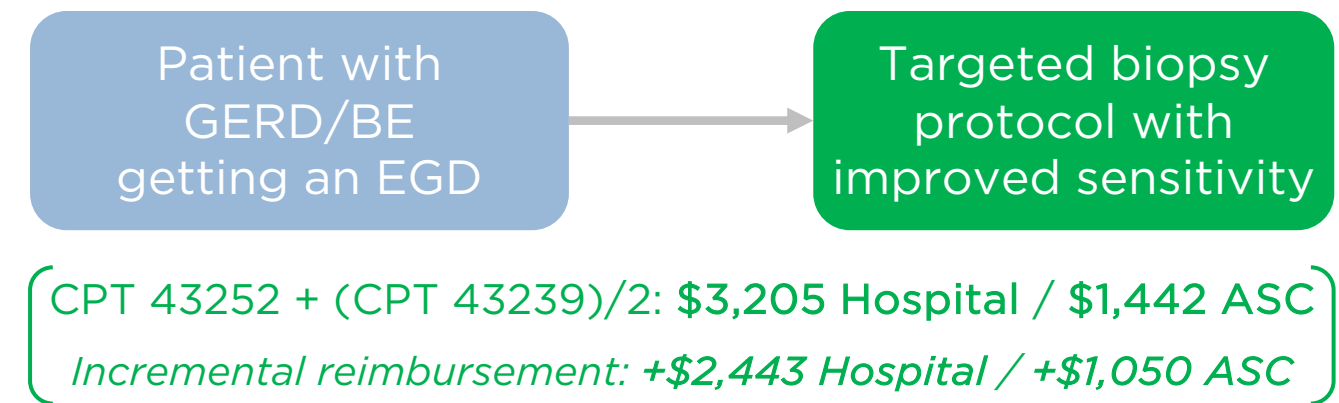
Setting	2019 Rate	2019 % Change
Hospital	\$2,824	+3%
ASC	\$1,245	+3%

Attractive Economics for Hospital and ASC Customers

WITHOUT Optical Endomicroscopy



WITH Optical Endomicroscopy



Favorable Economic Model for Cellvizio Customers
= Tailwind for System Adoption and Utilization

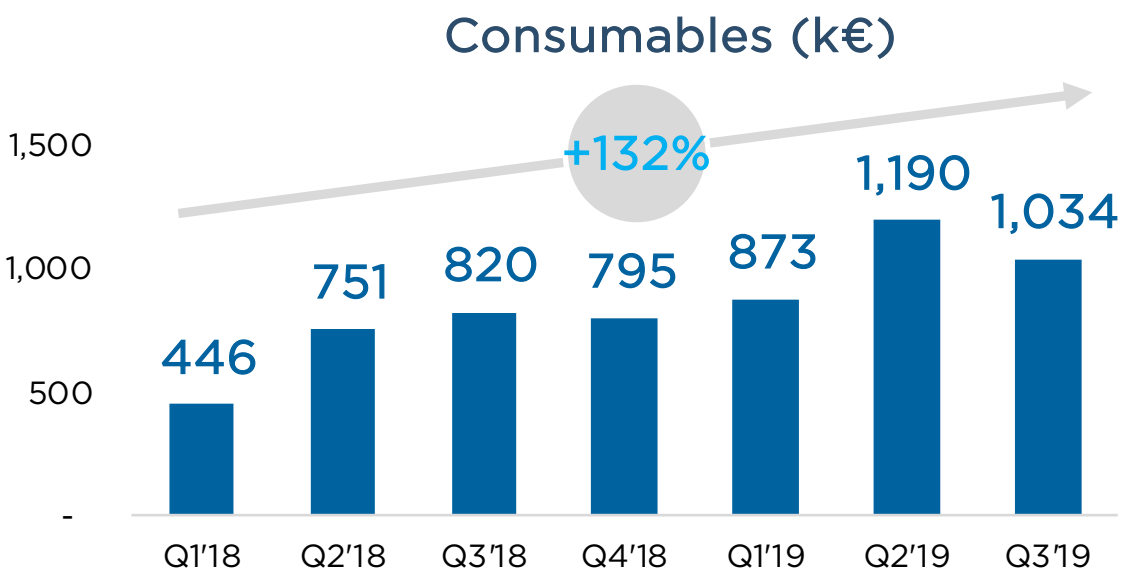
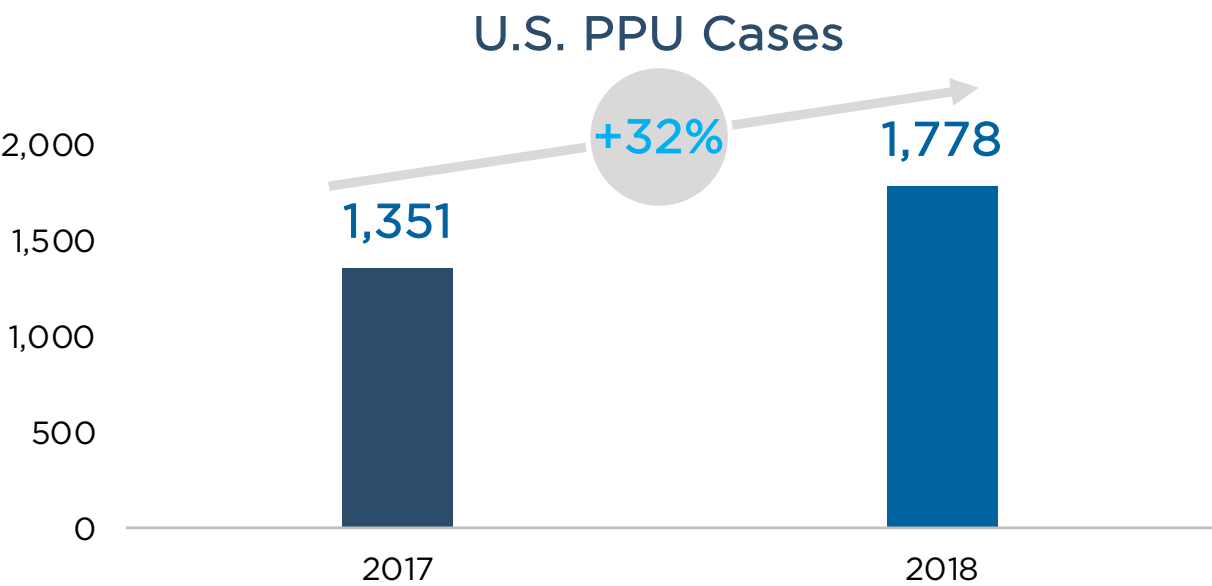
Executing a Focused U.S. Commercial Business Model: Placement + Pay-Per-Use

Revised Commercial Strategy

- Transitioned US strategy in late 2017 to offer placement of Cellvizio system with Pay-Per-Use (PPU) consumable probe contract
- New selling strategy enables physicians to utilize Cellvizio without upfront capital equipment purchase; provides attractive economic model for physicians and hospitals/ASCs

Positive trends in system placements AND strong demand (utilization) for consumable probes from GI accounts in hospitals/ASCs

Strategy Validated in 2018 and YTD 2019



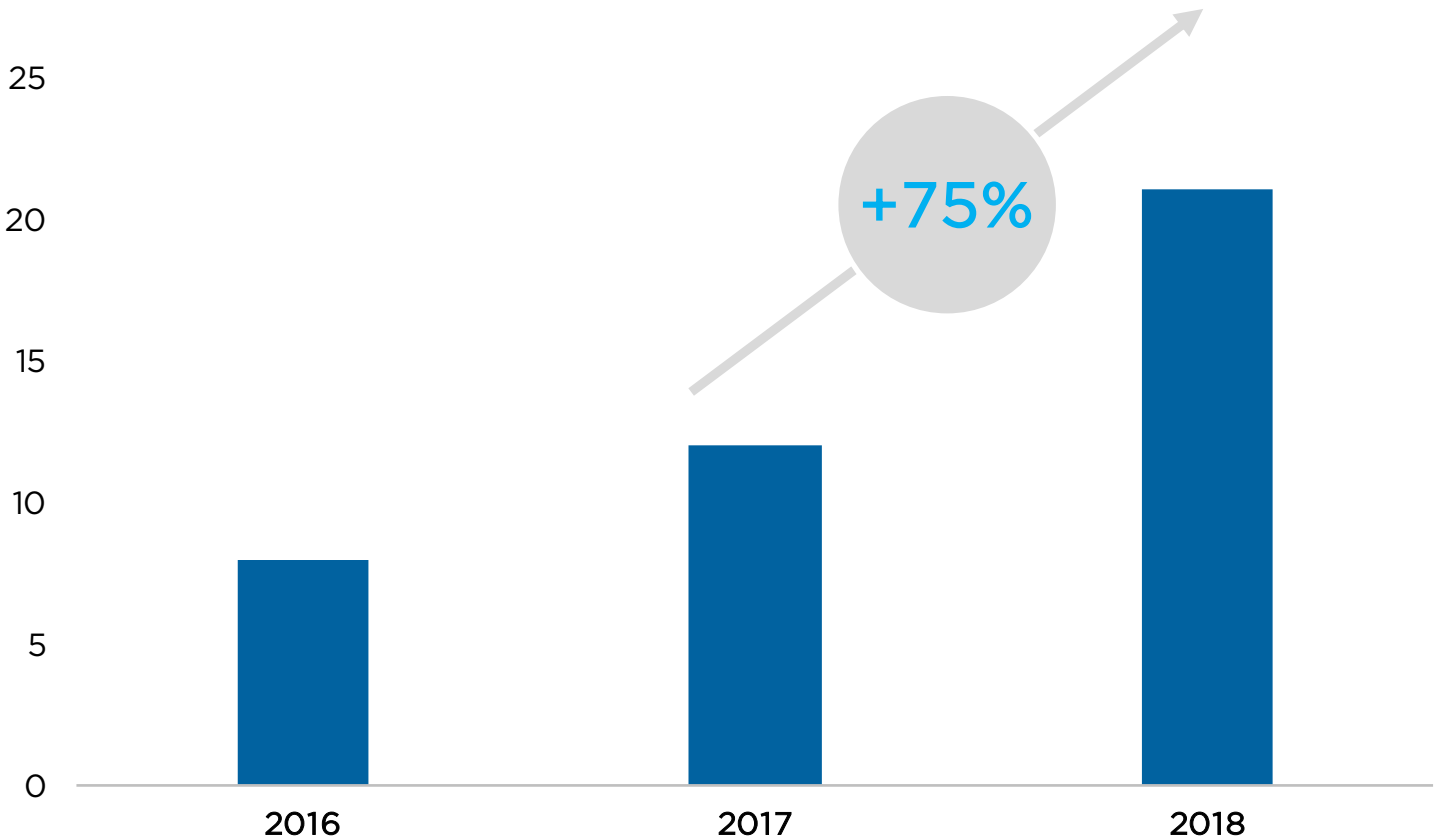
U.S. Commercial Team is Structured to Execute

New Sales Team in Place since February 2018

- VP of Sales: 1
- Divisional sales managers: 2
- Area sales managers: 12
- Clinical account managers: 6



U.S. Selling Professionals



New Sales Team in 2018 + Validated Strategy =
Poised for Strong Penetration of U.S. GI Hospitals/ASCs

Cellvizio Supported by Strong IP Protection and Clinical Validation

Cellvizio Technology Protected by 247 Issued Patents Globally

- Covering optics, optronics, image processing, and machine learning
- Additional 24 patents pending

Clinical Validation Portfolio of over 1,000 Studies and Publications

- Current imaging tools (HD-WLE, NBI) and untargeted conventional biopsies result in low diagnostic yield and poor sensitivity/specificity
- Since 2005, CLE's clinical contributions have been reported in more than 1,000 clinical publications worldwide on endomicroscopy

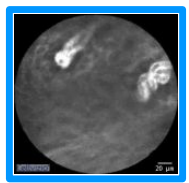
Demonstrated Clinical Validation

- Double the sensitivity vs. HD-WLE and NBI
- Triple the detection of dysplasia vs. HD-WLE and random biopsies
- Reduce diagnostic uncertainty of benign lesions down to 0%
- Improve diagnostic yield to reduce sampling error

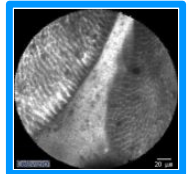
Sharma P. et al. Real-time Increased Detection of Neoplastic Tissue in Barrett's Esophagus with probe-based Confocal Laser Endomicroscopy: Final Results of a Multi-center Prospective International Randomized Controlled Trial. GIE 2011. Bertani H. et al. Improved Detection of Incident Dysplasia by Probe-Based Confocal Laser Endomicroscopy in a Barrett's Esophagus Surveillance Program. Digestive Diseases and Sciences, 2013. M. Canto, et al. In vivo endomicroscopy improves detection of Barrett's esophagus-related neoplasia: a multicenter international randomized controlled trial, GIE 2013. Richardson C. et al. Real-time diagnosis of Barrett's esophagus: a prospective, multicenter study comparing confocal laser endomicroscopy with conventional histology for the identification of intestinal metaplasia in new users. Surgical Endoscopy 2018. Desai, Madhav et al. Increasing prevalence of high-grade dysplasia and adenocarcinoma on index endoscopy in Barrett's esophagus over the past 2 decades: data from a multicenter U.S. consortium. GIE 2019.

Gastroenterology is the Primary Growth Driver Today, Multiple FDA Cleared Clinical Indications Will Drive Future Growth

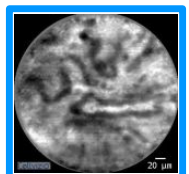
GASTROENTEROLOGY



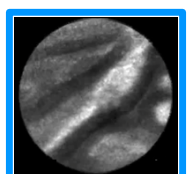
GERD/Barrett's Esophagus



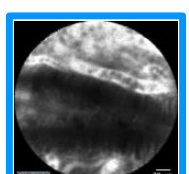
Early gastric cancer



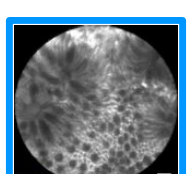
Biliary strictures



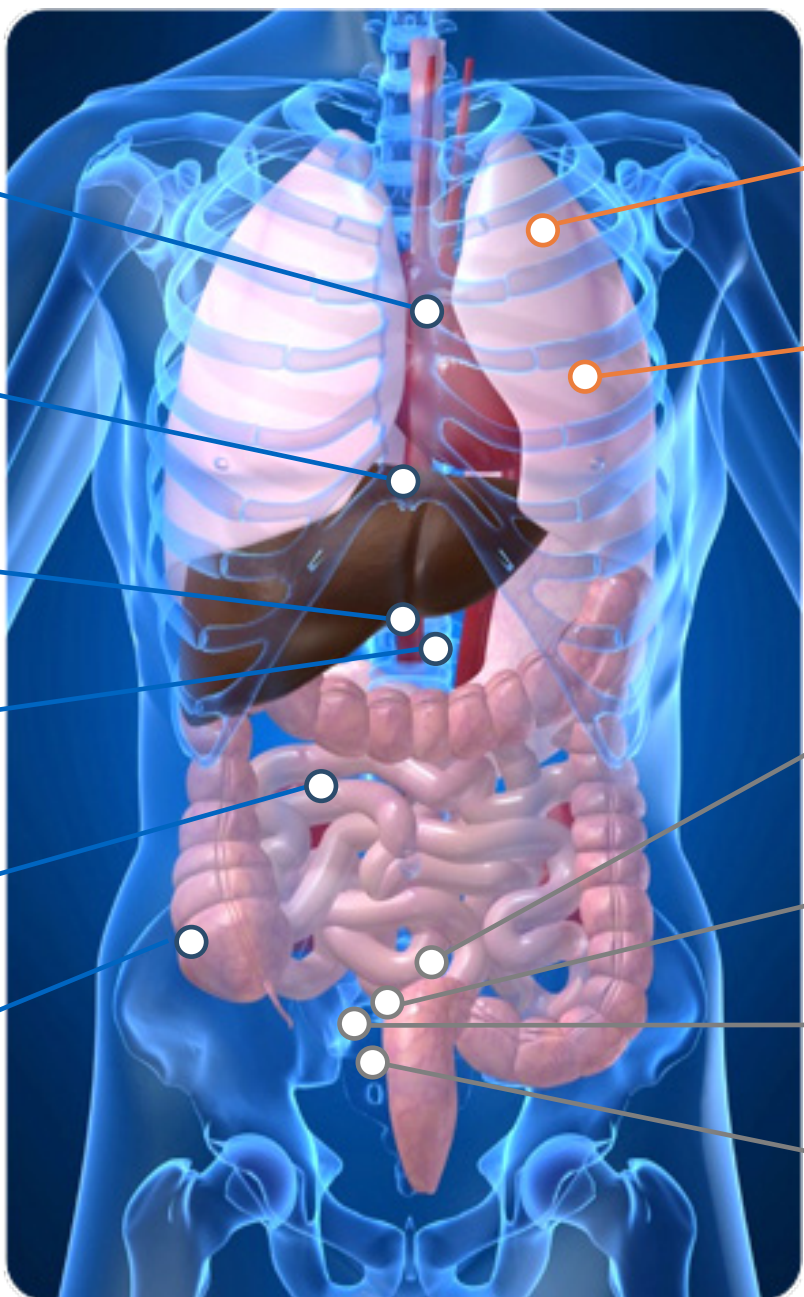
Pancreatic cysts



Food allergies

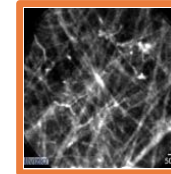


Inflammatory Bowel Diseases

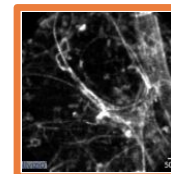


PULMONOLOGY

Lung cancer

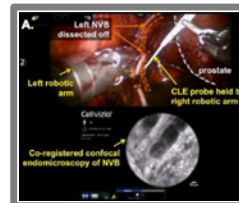


Peripheral nodules

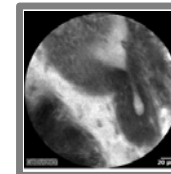


UROLOGY

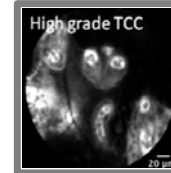
Prostatectomy



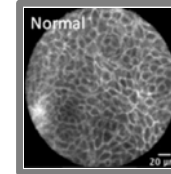
Upper tract urothelial cancer



Partial nephrectomy



Bladder cancer



100+ published Cellvizio studies with more than 8,800 patients across multiple indications

Formal Evaluation Process to Identify Next Commercial Focus-Area



- Formal, disciplined process to evaluate range of clinical indications
- Multi-step process, begins with screening, ends with commercially scaling the new indication
- First one for evaluation is interventional pulmonology
 - More than 240,000 annual lung biopsy procedures in the US alone, presenting compelling market opportunity
 - 510(k) clearance for Cellvizio AQ-Flex™ 19 Confocal Miniprobe™ designed to be used through existing bronchoscopes, trans-bronchial needles and other bronchoscope accessories
 - AQ-Flex™ 19 also designed for use with emerging platforms such as the Monarch™ robot from Auris/J&J and Ion™ robot from Intuitive

Important strategic evaluation process to identify
the next growth engine for Mauna Kea

Management Team & Board of Directors

Management Team



Robert L. Gershon
Chief Executive Officer

Bovie Medical,
Covidien
(Medtronic), Henry
Schein



Christophe Lamboeuf, CPA
Chief Financial Officer

Intrasense, General
Electric, Ricoh, CS
Telecom, Toshiba



François Lacombe, Ph.D.
Chief Scientific Officer

Astrophysics
programs: ISOCAM,
ADONIS, NAOS



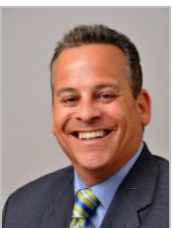
Jack McCarthy
Chief Marketing Officer

Bovie Medical,
Z-Medica, Covidien
(Medtronic)



Bruno Villaret
VP, International Sales

Tyco, Saint-Gobain



Larry Weiss
VP, U.S. Sales

Christie Medical,
GE Healthcare,
Abbott Diagnostics

Board of Directors



Sacha Loiseau, Ph.D., Chairman of the Board
Founder of Mauna Kea Technologies



Robert L. Gershon, Director
Chief Executive Officer of Mauna Kea Technologies



Christopher McFadden, CFA, Director
Managing Director of Kohlberg Kravis Roberts (KKR)



Jennifer F. Tseng, M.D., Director
*Chief and Chair of Surgery,
Boston University School of Medicine*



Joseph DeVivo, Director
Chief Executive Officer of InTouch Health, Inc.



Molly O'Neill, Director
*Chief Growth and Strategy Officer,
Medforth Global Healthcare Education Group*

Sales and Financial Performance

September 2019 Year-to-Date



2019 September Year-to-Date Sales: 24% Growth vs. Last Year

2019 September Year-to-Date Sales

	Actual	Last Year	V LY%
Systems	1,911	1,809	6%
Consumables	3,097	2,017	54%
<i>O/W PPU</i>	1,289	563	129%
Services	732	815	-10%
Total	5,739	4,641	24%

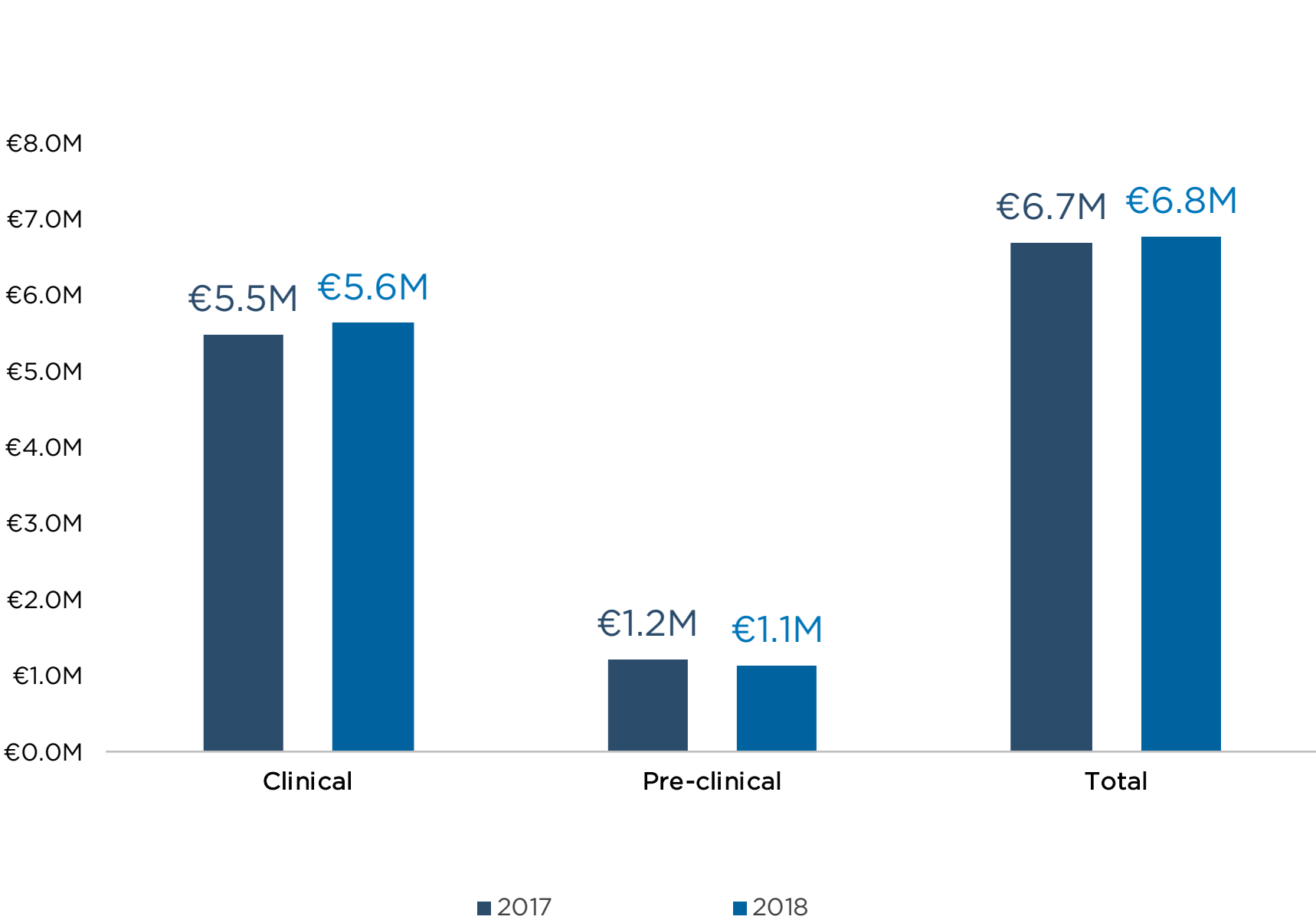
	Actual	Last Year	V LY%
APAC	2,058	1,310	57%
EMEA & ROW	1,132	1,066	6%
US & Canada	2,549	2,265	13%
Total	5,739	4,641	24%

All figures in € thousands

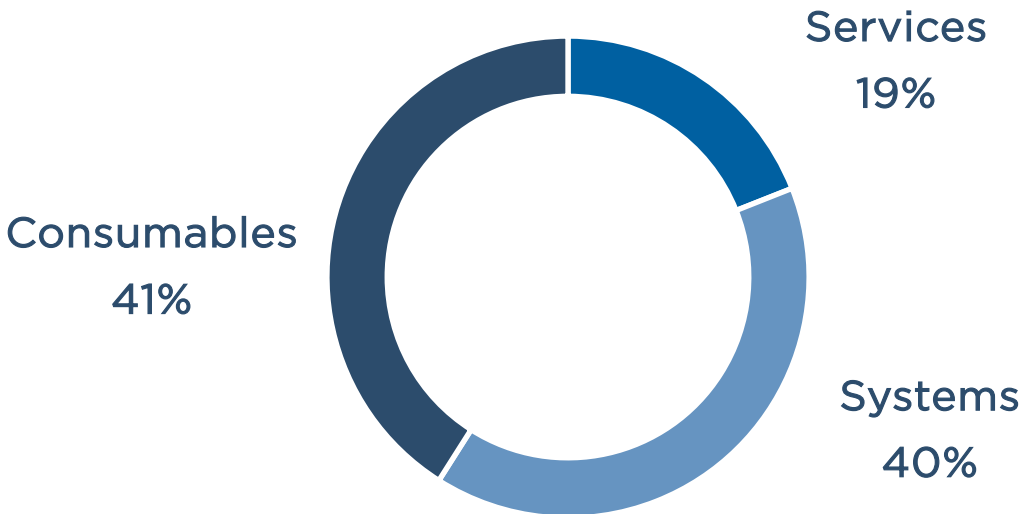
- Consumables grew 54% and represents over 54% of overall revenue
 - Progress in expanding pay-per-use model in the U.S. GI market during 2018 resulted in a larger installed base of systems which are driving the strong demand for consumables this year
- PPU revenue growth of 129% in the U.S. was the largest contributor to total Company revenue growth YOY
- Sales in Asia-Pacific region increased 57% YOY fueled by sales of both new systems and consumables

€6.8M 2018 Revenue Summary

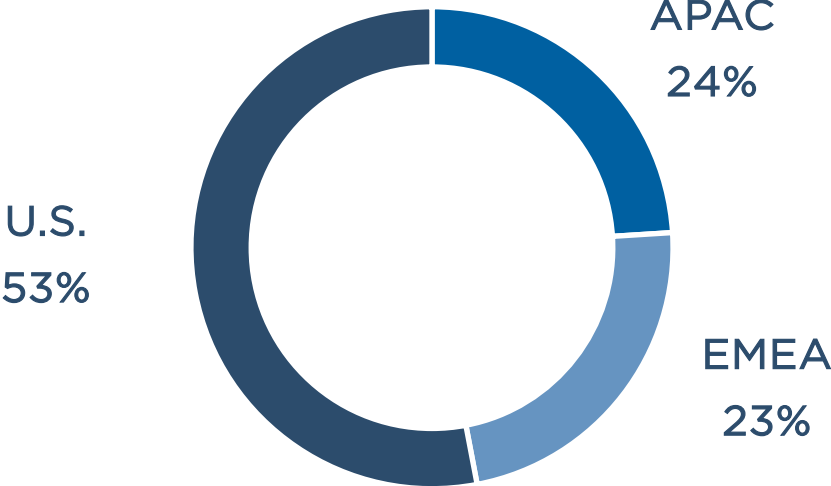
Breakdown



By product



By region

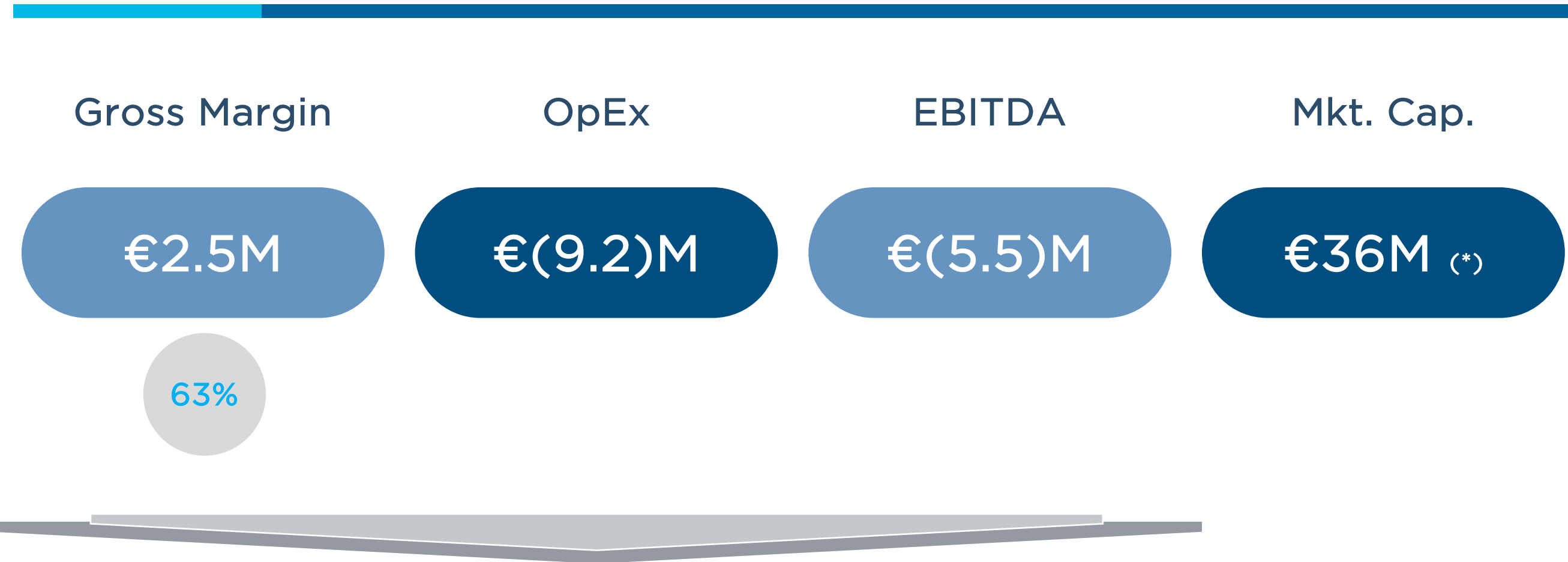


Investment Highlights: Innovative Technology + Focused Strategy

- 1 Cellvizio®: a transformational probe-based Confocal Laser Endomicroscopy (CLE) platform with a broad IP protection: 247 issued and 24 pending patents on the technologies
- 2 U.S.-focused growth strategy fueled by proven technology, focused commercial strategy, strong team, broad clinical validation and attractive Medicare reimbursement
- 3 A focused strategy on:
 - Large and growing gastrointestinal market with a U.S. focused sales strategy to drive consumable growth
 - Drive revenue growth outside the U.S. in a targeted fashion to maximize resource allocations
 - Evaluate the interventional pulmonology market as a new clinical indication for the next commercial focus-area and growth driver of Mauna Kea
- 4 Robust R&D pipeline to drive growth through application and product expansion
- 5 Strong regulatory support: Approved in 40+ countries; 16 U.S. FDA 510(k) clearances
- 6 New seasoned US-based executive leadership to drive commercial acceleration

Appendix

June 2019 P&L



- First Half Sales up 45% in half Versus First Half 2018
- EBITDA loss stable compared to last year thanks to sales growth and well-managed OpEx
- 2019 Cash flows impacted by IPF debt repayment .

(*) As of September 23rd.

Strong Sales and Well-Managed OpEx

P&L STATEMENT	2019A	2018A	Δ vs. N-1 (k€)	Δ vs. N-1 (%)
Sales	3 937	2 707	1 230	45%
Gross Margin	2 468	1 720	748	43%
Other revenues	576	525	51	10%
R&D Expenses	(583)	(633)	50	(8)%
M&S Expenses	(1 264)	(1 172)	(92)	8%
G&A Expenses	(925)	(1 049)	124	(12)%
Total Expenses	(2 772)	(2 854)	82	(3)%
R&D Payroll	(1 271)	(1 253)	(18)	1%
M&S Payroll	(3 060)	(2 701)	(359)	13%
G&A Payroll	(1 403)	(952)	(451)	47%
Total Payroll	(5 734)	(4 906)	(828)	17%
EBITDA	(5 463)	(5 516)	53	(1)%
R&D Depreciation	(196)	(348)	152	(44)%
M&S Depreciation	(272)	(504)	232	(46)%
G&A Depreciation	(250)	(67)	(183)	273%
Depreciation	(719)	(920)	201	(22)%
Share based payment	(432)	(43)	(389)	905%
EBIT	(6 614)	(6 479)	(135)	2%

R&D total expenses	(2 050)	(2 234)
M&S total expenses	(4 596)	(4 377)
G&A total expenses	(2 579)	(2 068)
Total expenses	(9 225)	(8 679)
GM rate	63%	64%
M&S Expenses vs sales	(117)%	(162)%

- Strong half year sales grew 45% compared to last year
- Total expenses (without payroll) decreased 3% vs. prior year
- Decrease in R&D of €0.2M, or 9%, due to capitalization on the balance sheet of expenses
- Increase of €0.5M in administrative payroll expenses reflecting the full effect of investments made in the second half 2018 to strengthen the management team

Balance Sheet

ASSETS (in K€)	June 2019	Dec. 2018
Intangible assets	1 862	1 838
Property, plant, and equipment	3 117	1 985
Non-current financial assets	173	133
Total of non-current assets	5 152	3 956
Inventories & Work in progress	2 387	2 456
Trade receivables	2 028	1 643
Other current assets	1 662	3 019
Current financial assets	57	64
Cash and cash equivalents	0	8 623
Total of current assets	6 135	15 806
TOTAL OF ASSETS	11 288	19 762

LIABILITIES (in K€)	June 2019	Dec. 2018
Equity	331	7 979
Long-term loans and borrowings	3 361	6 457
Non-current provisions	416	422
Total of non-current liabilities	3 777	6 879
Short-term loans and borrowings	3 011	600
Trade payables	1 722	2 087
Other current liabilities	2 447	2 216
Total of current liabilities	7 181	4 904
TOTAL LIABILITIES	11 288	19 762

- Inventories slightly decreased compared to Dec. 2018
- Receivables reflected the strong sales momentum at the end of June

- Repayment of IPF Debt drove the decrease in long-term borrowings
- Timing between IPF Repayment and EIB funds received in early July explained the temporary negative cash position at end of June

Cash Flow Statement

In K€	June 2019	June 2018
Ebitda (*)	(4 947)	(5 906)
Δ in inventories	92	(521)
Δ in trade receivables	(378)	433
Δ in trade payables	(366)	238
Δ in other receivables and payables	1 472	118
Δ in working capital	820	268
Operating cash flows	(4 127)	(5 638)
Capex (incl. Loans and grants)	(720)	(222)
Free cash Flows	(4 847)	(5 860)
Capital increase	20	3 799
Δ in financial debt - IPF	(4 000)	
Net financial interest paid	(503)	(175)
IPF penalties and others	(1 789)	
Other	(192)	(90)
Cash flow from financing activities	(6 464)	3 534
Net FX differences	6	5
Net cash flows	(11 306)	(2 320)
Cash BoP	8 623	17 453
Cash EoP	-2 683	15 132

(*) difference with Ebitda in P&L due to non cash provision for warranty

- 2019 Operating cash flows excludes non recurring finance expenses to IPF
- Increase in Capex reflected installation of PPU systems
- Negative cash flows from financing due to repayment of IPF debt
- Cash used in operating and investing activities totaled €4.8M in first half compared to €5.9M last year
- Timing between IPF repayment and EIB funds received in early July explained the temporary negative cash position at end of June. As of July 3rd, the cash position was €8.8M after receiving the first tranche of €11.5M from EIB.

Thank You